UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

LIFESCAN SCOTLAND, LTD., et al.,

Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC, et al.,

Defendants.

Case No. 11-cv-04494-WHO

**CLAIM CONSTRUCTION ORDER**

Re: Dkt. Nos. 415, 417

## INTRODUCTION

Plaintiffs LifeScan Inc. and LifeScan Scotland, Ltd. (collectively, "LifeScan") allege that defendants Shasta Technologies, LLC, Conductive Technologies, Inc., Instacare Corp. and Pharmatech Solutions, Inc. infringe U.S. Patents Numbers 5,708,247 (the "'247 patent") and 6,241,862 (the "'862 patent"),[1] which relate to blood glucose monitoring systems for use by

[1] The amended complaint also asserts that defendants infringe U.S. Patent Number 7,250,105. *See* Dkt. No. 170. That patent is not at issue in this claim construction proceeding. Per the parties' stipulation, the causes of action regarding the '105 patent were stayed in October 2013 pending final decision by the Patent Trials and Appeals Board ("PTAB") in the then-pending *inter partes* review ("IPR") of '105 patent. Dkt. No. 372. The stay order stated that "[w]hen the PTAB issues a final decision in the IPR concerning the '105 Patent, the Court, on the request of any party, may consider whether the stay provided in this paragraph should, or should not, continue during the pendency of any appeals from that final decision." *Id.* On August 7, 2014, after the present claim construction briefing was complete, defendants filed a "Notice of Final IPR Decision [of the '105 patent] and Automatic Lifting of Stay." Dkt. No. 425. LifeScan promptly pointed out that the stay order did not call for an "automatic lifting of stay." Dkt. No. 429. LifeScan subsequently stated why, in its opinion, the stay should remain in effect pending appeal from the IPR of the '105 patent. Dkt. No. 437. Defendants have not responded to LifeScan's argument that the stay should remain in place during the appeal. If defendants contend that the stay should be lifted, notwithstanding the appeal, they shall file an administrative motion seeking that relief within 20 days of this order.

people with diabetes. The parties have requested that the Court construe six disputed terms in the asserted claims. Having fully considered the parties' arguments and submissions, I construe the disputed terms as set forth below.

## BACKGROUND

The patents at issue relate to disposable test strips for glucose monitors. The '247 patent is entitled "Disposable Glucose Test Strips, and Methods and Compositions for Making Same" and purports to provide "an improved disposable glucose test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood from a patient and performs an electrochemical analysis of the amount of glucose in the sample." '247 patent at 2:39-44 (Dkt. No. 409, Ex. B). The '247 patent was filed on February 14, 1996 and issued on January 13, 1998.

The '862 patent is a continuation-in-part of the '247 patent and is entitled "Disposable Test Strips with Integrated Reagent/Blood Separation Layer." '862 patent (Dkt. No. 409, Ex. C). The '862 patent was filed on January 12, 1999 and issued on June 5, 2001.

The parties seek construction of three claim terms or phrases in the '247 patent and three claim terms or phrases in the '862 patent. In addition, defendants contend that four of the terms are indefinite. The claims at issue appear in the appendix at the end of this order.

## LEGAL STANDARD

Claim construction is a matter of law for the court's determination. *Markman v. Westview Instr., Inc.*, 517 U.S. 370, 372 (1996). In order to construe claim terms, "the trial court must determine the meaning of any disputed words from the perspective of one of ordinary skill in the pertinent art at the time of filing." *Chamberlain Grp., Inc. v. Lear Corp.*, 516 F.3d 1331, 1335 (Fed. Cir. 2008).

The words of a claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (citations omitted). But the ordinary and customary meaning of a claim term cannot be determined in a vacuum. Intrinsic evidence—the claims, specification, and the prosecution history of the patent—"is the primary tool to supply the context for interpretation of disputed claim terms." *V-Formation, Inc. v. Benetton Grp. SpA*, 401 F.3d 1307, 1310 (Fed. Cir. 2005); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582

(Fed. Cir. 1996) ("It is well-settled that, in interpreting an asserted claim, the court should look first to the intrinsic evidence of record, *i.e.*, the patent itself, including the claims, the specification and, if in evidence, the prosecution history.").

The "specification necessarily informs the proper construction of the claims." *Phillips*, 415 F.3d at 1316. It "is the single best guide to the meaning of a disputed term, and . . . acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* at 1321 (quotations omitted). However, "[t]hat claims are interpreted in light of the specification does not mean that everything expressed in the specification must be read into all the claims." *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983). "The claim, not the specification, measures the invention." *Id*. (citation omitted). For example, "merely because the specification only describes one embodiment is not a sufficient reason to limit the claims to that embodiment." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1372 (Fed. Cir. 2003). Nonetheless, "claims must be construed so as to be consistent with the specification." *Phillips*, 415 F.3d at 1316.

The Federal Circuit has acknowledged "that there is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." *Decisioning.com, Inc. v. Federated Dep't Stores, Inc.*, 527 F.3d 1300, 1307 (Fed. Cir. 2008) (internal citations omitted). The Federal Circuit instructs that "attempting to resolve that problem in the context of the particular patent is likely to capture the scope of the actual invention more accurately than either strictly limiting the scope of the claims to the embodiments disclosed in the specification or divorcing the claim language from the specification, and, thus, that there can be no magic formula or catechism for conducting claim construction." *Id.* at 1307-08 (citing *Phillips*, 415 F.3d at 1323-24). Consequently, courts "must read the specification in light of its purposes in order to determine whether the patentee is setting out specific examples of the invention to accomplish those goals, or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." *Decisioning.com*, 527 F.3d at 1308 (internal citations omitted). The court's focus is on "understanding how a person of ordinary skill in the art would understand the claim terms." *Id.*

"In most situations, an analysis of the intrinsic evidence alone will resolve any ambiguity in a disputed claim term." *Vitronics*, 90 F.3d at 1583. In those circumstances, it is improper to rely on extrinsic evidence, such as dictionaries, treatises, and expert testimony. *Id.* If the intrinsic evidence fails to resolve any ambiguity in the claim language, the court may rely on extrinsic evidence. *Id.* While extrinsic evidence may guide the meaning of a claim term, such evidence is less reliable than intrinsic evidence. *See Phillips*, 415 F.3d at 1318-19.

## DISCUSSION

### I. DEFENDANTS' INDEFINITENESS ARGUMENTS ARE MORE APPROPRIATELY ADDRESSED AFTER THE CLOSE OF DISCOVERY

Defendants argue that several of the disputed claim terms are indefinite, rendering the claims invalid. LifeScan responds that the asserted claims are not indefinite and, as an initial matter, the indefiniteness arguments are premature and should be addressed after the close of discovery. For the reasons stated below, I agree with LifeScan that the indefiniteness arguments are more appropriately addressed on summary judgment after the close of discovery.

"[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S. Ct. 2120, 2124 (2014) (citing 35 U.S.C. § 112, ¶ 2).[2] To evaluate an indefiniteness claim, I must (i) evaluate the claim from the perspective of someone skilled in the relevant art; (ii) read the claim in light of the patent's specification and prosecution history; and (iii) measure definiteness from the viewpoint of a person skilled in the art at the time the patent was filed. *Nautilus*, 134 S. Ct. at 2128 (citations omitted).

"[A] determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims." *In re Aoyama*, 656 F.3d 1293, 1299 (Fed. Cir. 2011) (citation omitted). Accordingly, it may be appropriate to address

[2] The second paragraph of Section 112 is now Section 112(b). *Nautilus* is based on the Patent Act prior to the 2011 amendments to the Patent Act based on the filing date of the patent at issue. The Supreme Court noted, however, that the 2011 "amendments modified §§ 112 and 282 in minor respects not pertinent here." *Nautilus*, 134 S. Ct. at 2125 n.1.

indefiniteness issues at the claim construction stage, rather than at summary judgment. For example, in *Prolifiq Software Inc. v. Veeva Sys. Inc.*, 2014 WL 3870016, at *8 (N.D. Cal. Aug. 6, 2014), Judge Illston noted that "[a]lthough expert testimony is generally helpful in determining whether a claim is indefinite, expert testimony is not always required to make that determination." Judge Illston rejected an argument that it was premature to determine indefiniteness without expert testimony, explaining that the term at issue in *Prolifiq Software* "allows the scope of the invention to be determined by the unrestrained, subjective opinion of the person practicing the invention, [and therefore] no one, including a person skilled in the art, can determine with reasonable clarity the scope of the invention." *Id*. (citation omitted).

In contrast, where extrinsic evidence of the perspective of someone skilled in the art is relevant to the indefiniteness inquiry, it is appropriate to defer the indefiniteness determination until after the close of discovery. *See, e.g., Intergraph Hardware Technologies Co. v. Toshiba Corp.*, 508 F. Supp. 2d 752, 773 n.3 (N.D. Cal. 2007) ("The parties appear to agree on the corresponding structure, though Toshiba argues that the structure is too indefinite. This indefiniteness argument is inappropriate at the claim construction stage."); *Waddington N. Am., Inc. v. Sabert Corp.*, 2010 WL 4363137, at *3 (D.N.J. Oct. 27, 2010) ("It may be true that determining the indefiniteness of claim language is a question of law 'that is drawn from the court's performance of its duty as the construer of patent claims,' which is the same duty that gives rise to the *Markman* hearing. However, this does not outweigh the previous practical considerations that militate against determining indefiniteness prior to the end of fact or expert discovery.") (citation omitted); *cf Ateliers de la Haute-Garonne v. Broetje Automation-USA Inc.*, 2014 WL 491534, at *2 (D. Del. Feb. 4, 2014) (noting that it is "appropriate for the Court to consider extrinsic evidence relating to whether one of ordinary skill in the art would be capable of understanding the claim containing the allegedly indefinite term").

Defendants contend that the term "a filler having both hydrophilic and hydrophobic surface regions," which appears in claims 1 and 24 of the '247 patent, is indefinite because "neither the claim language nor the specification provide any guidance whatsoever as to the relative proportion of hydrophobic surface regions to hydrophilic surface regions – *i.e*. the degree of hydrophobicity –

required to practice the patent." Dkt. No. 417 at 9. Defendants also contend that the term "a filler . . . that forms a network upon drying," which appears in the same claims, is indefinite because it is defined only by its function, i.e., forming a network upon drying.

I cannot conclude on the record before me that the claims at issue fail to inform someone skilled in the art about the scope of the invention with reasonable certainty. For example, the specification of the '247 patent provides guidance regarding the required levels of hydrophobicity: it identifies substances that are too hydrophobic (C18-modified silica) and others that are the correct level of hydrophobic (Cab-O-Sil TS610). *See* '247 patent at 4:12-26. Expert testimony will help inform whether this or other information in the patent is insufficient for someone skilled in the art to determine the scope of the invention with reasonable certainty.[3]

Likewise, I cannot conclude on the record before me that the term, "a filler . . . that forms a network upon drying," recites a function and renders the claims indefinite.[4] *See, e.g., Lighting World, Inc. v. Birchwood Lighting, Inc.*, 382 F.3d 1354, 1359-60 (Fed. Cir. 2004) (in order for a claim to be defined by structure rather than function, "it is sufficient if the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure, even if the term covers a broad class of structures and even if the term identifies the structures by their function.").

Defendants indefiniteness objections to the terms, "a[n] . . . integrated reagent/blood separation layer" and "matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species," which appear in claims 1, 2, 11, 22, and 23 of the '862 patent, are premature for the same reasons. Expert discovery will inform whether these claims would be indefinite to a person skilled in the art. Defendants may renew their indefiniteness arguments after

[3] Defendants reference the testimony of Dr. Wilson in support of their indefiniteness argument. But the referenced testimony relates to declarations submitted by Dr. Wilson in connection with reexamination of the '247 patent in which Dr. Wilson addressed defendants' assertion that the patent was obvious in view of certain prior art references. I have not yet set deadlines for expert reports or expert discovery in this case.

[4] LifeScan asserts that this term is not functional because it "simply tells the reader *when* the network is formed, *i.e.*, the network is formed when the filler dries." Dkt. No. 421 at 9 (emphasis in original).

the close of discovery in a motion for summary judgment.[5]

## II. CONSTRUCTIONS OF DISPUTED TERMS

### A. *A filler having both hydrophilic and hydrophobic surface regions* ('247 patent, claims 1, 24)

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| additive having some surface regions that lack an affinity for water and some surface regions that have an affinity for water | **Objection**: Compound defined by its characteristics only is indefinite.<br>**Alternative Constructions:**<br>1. Modified or treated silica.<br>2. A filler that has a portion of it surface region that easily dissolves when hydrated and other portions of its surface that does not such that the *network*[6] remain intact and does not dissolve upon rewetting by the blood sample and renders the test strip substantially insensitive to the hematocrit of the patient.[7] | additive having some surface regions that lack an affinity for water and some surface regions that have an affinity for water |

LifeScan's proposed construction substitutes the term "additive" for the term "filler" and restates the term "hydrophilic and hydrophobic surface regions" as "some surface regions that lack an affinity for water and some surface regions that have an affinity for water." Defendants do not contend that LifeScan's proposed definitions are inaccurate. Rather, defendants argue that the

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[5] The indefiniteness issue may be renewed in a motion for summary judgment. Any disputed questions of fact will not preclude summary judgment of indefiniteness. Rather, any disputed facts will be resolved by me, along with the ultimate question of indefiniteness. *See, e.g., Thought, Inc. v. Oracle Corp.*, 12-cv-05601-WHO, 2014 WL 5408179, at *8 (N.D. Cal. Oct. 22, 2014) ("because indefiniteness is a question of law for the court to determine, I must resolve any disputed issue of material fact based on the evidence before me").

[6] Terms subject to construction are italicized.

[7] Defendants did not support their second proposed construction in their briefing or at the claim construction hearing. I likewise do not address the second proposed construction.

patentee, pursuant to the doctrine of prosecution history disclaimer, limited the filler at issue to silica, the preferred embodiment disclosed in the specification.

Under the doctrine of prosecution history disclaimer, "when the patentee unequivocally and unambiguously disavows a certain meaning to obtain a patent . . . the meaning of the claim [is narrowed] consistent with the scope of the claim surrendered." *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013). Relatedly, "when the specification uses a single embodiment to enable the claims, courts should not limit the broader claim language to that embodiment unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest execution or restriction.'" *Trading Technologies Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1352 (Fed. Cir. 2010) (internal punctuation and citation omitted).

Defendants argue that the patentee disavowed any construction of "filler" other than silica when, during the prosecution history, it agreed to an examiner's amendment to Claim 17 which inserted the term "silica" before "filler" in order to overcome rejection of that claim, i.e., a "*silica* filler having both hydrophilic and hydrophobic surface regions." The examiner's statement of reasons for allowance noted that "[t]he composition of claim 17 was changed by amendment to correct the indefiniteness of the claim with respect to the filler which recited a physical property having no specific composition." Dkt. No. 416-5 at 11. Claim 17 is not asserted here, but defendants argue that the disclaimer of Claim 17 applies to claim 1 because the claims both contain the term "filler having hydrophobic and hydrophilic surface regions."

I am not convinced that the patentee of the '247 patent unequivocally and unambiguously disavowed a meaning of filler other than silica in claims 1 and 24, the claims at issue here. Notably, unlike claim 17, claims 1 and 24 were issued without addition of the term "silica." The Federal Circuit instructs that "when a patent claim does not contain a certain limitation and another claim does, that limitation cannot be read into the former claims." *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1326 (Fed. Cir. 2003) (citation omitted).

Moreover, the examiner initially rejected claims 1 through 35 (including claims 1 and 24) on the grounds that the only example of enabling filler disclosed in the patent was silica. Dkt. No.

416-4 at 33. But the examiner withdrew the objection after the patentee responded that it had no obligation to provide enabling examples. The examiner's statement of reasons for allowance states that "[t]he prior art of record fails to teach the key to the applicants instant invention which is the inclusion of a filler having hydrophobic and hydrophilic surface regions." Dkt. No. 416-5 at 11. This prosecution history indicates that the examiner was directly focused on the limitations disclosing filler and suggests that the examiner determined that Claim 17 was indefinite without disclosing silica, but that claims 1 and 24 did not need to disclose silica in order to avoid indefiniteness. Indeed, claims 3 and 26, which are not asserted in this case, recite the test strip of claim 2 and the method of claim 25, respectively, but add the limitation: "wherein the filler is silica."[8] *See* '247 patent at 7:46, 8:52. Limiting the filler disclosed in claims 2 and 25 to silica would render claims 3 and 26 superfluous. In light of the attention the examiner and the patentee paid to all the limitations involving filler, and that the examiner required that silica be disclosed in claim 17 but not claims 1 and 24, I cannot conclude that the patentee unequivocally and unambiguously disavowed a meaning of filler broader than silica in claims 1 and 24.[9]

LifeScan's proposed construction employs clear, easily-understood language and its accuracy has not been challenged by defendants. I accordingly adopt LifeScan's proposed construction: "additive having some surface regions that lack an affinity for water and some surface regions that have an affinity for water."

[8] Claims 2 and 25 are dependent on claims 1 and 24, respectively, both of which contain the disputed term at issue here: "a filler having both hydrophilic and hydrophobic surface regions."

[9] The record before me does not state why the examiner determined that claim 17 was indefinite without disclosing silica, but claims 1 and 24 were not. I note, however, that claim 17 is directed to an "aqueous composition," whereas claims 1 and 24 are directed to a test strip and a method for making the test strip.

**B. *Network* ('247 patent, claims 1, 24)**

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| ordinary meaning<br>or<br>structure that provides a barrier to the passage of red blood cells | A netting, mesh, lattice or honeycomb structure having physically interconnected strands that form porous pathways. | structure |

LifeScan proposes that "network" be given its ordinary meaning (not construed) or construed as "structure that provides a barrier to the passage of red blood cells." LifeScan's proposed construction includes language which relates to the purpose of the "network," i.e., "provides a barrier to the passage of red blood cells." The purpose of the network is addressed below in the construction of "a filler . . . that forms a network upon drying." There is no reason to also construe the term "network," standing alone, in a manner which incorporates its purpose. Stripped of that extraneous language, LifeScan's proposed construction is that the term "structure" be substituted for the claim term "network."

Defendants also employ the term "structure" in their proposed construction: "a netting, mesh, lattice or honeycomb *structure* having physically interconnected strands that form porous pathways." However, defendants' proposed construction includes descriptions of the structure imported from the specification. For example, the specification states that "the dual nature of the material causes it to form layers of two-dimensional networks which take form as a kind of honeycomb." '247 patent at 4:37-39. Defendants provide no compelling reason to import those examples from the specification into the claim. *See e.g., In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1372 (Fed. Cir. 2007) ("Absent some clear intent to the contrary, this court does not import examples from the specification into the claims.").

Consistent with the parties' constructions, but excluding qualifying language proposed by the parties which is not warranted, I construe the claim term "network" as "structure."

**C. *A filler . . . that forms a network upon drying* ('247 patent, claims 1, 24)**

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| Additive that forms a structure that provides a barrier to the passage of red blood cells upon drying | **Objection:** Compound defined by its functionality only is indefinite.<br>**Alternative Constructions:**<br>1. Sol-gel silica-- silica that forms a *network* upon drying through a sol-gel process that allows the glucose from a blood sample to pass into the layer while excluding the red blood cells of from the layer to provide a glucose reading that is essentially independent to variability in red blood cell counts of patients.<br>2. A filler that forms a *network* through a sol-gel process that allows the glucose from a blood sample to pass into the layer while excluding the red blood cells of from the layer to provide a glucose reading that is essentially independent to variability in red blood cell counts of patients. | Additive that forms a structure upon drying that excludes red blood cells while allowing glucose to pass through |

LifeScan proposes that "a filler . . . that forms a network upon drying" be construed as "additive that forms a structure that provides a barrier to the passage of red blood cells upon drying." A portion of this construction — "additive that forms a structure . . . upon drying" — is consistent with the term's plain language and the constructions of the terms "filler . . ." and "network" discussed above.

However, the remaining proposed language — "that provides a barrier to the passage of red blood cells" — is not inherent in the disputed claim language itself, but describes the function or objective of the network. Defendants likewise propose language which describes the function or objective of the network, i.e., "allows the glucose from a blood sample to pass into the layer

while excluding the red blood cells." In its reply brief, LifeScan states that "[i]t is acceptable to LifeScan, however, for the Court to accept defendants' assertion that a 'network' is a filtering mechanism formed from aggregated or interconnected particles that excludes red blood cells while permitting the through passage of glucose." Dkt. No. 421 at 12.

As the parties appear to agree that the term should incorporate a purpose of this limitation, I will construe the term consistent with its plain language, the constructions addressed above, and the portions of its purpose to which the parties agree. Accordingly, I construe "a filler . . . that forms a network upon drying" as an "additive that forms a structure upon drying that excludes red blood cells while allowing glucose to pass through."

**D. *A[n] . . . integrated reagent/blood separation* layer ('862 patent, claims 1, 2, 11, 22, 23)**

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| A single layer that contains reagents, is permeable to the analyte, and provides a barrier to the passage of red blood cells | **Objection:** Compound defined by its functionality only is indefinite.<br>**Alternative Constructions:**<br>1. Silica combined with reagents through a sol-gel process that allows the glucose to pass into the layer while excluding the red blood cells of the same blood sample to provide a glucose reading that is essentially independent to variability in red blood cell counts of patients.<br>2. A layer created using a sol-gel process that includes a reagent that allows glucose to pass into the layer while excluding the red blood cells of the same blood sample to provide a glucose reading that is essentially independent to variability in red blood cell counts of patients. | A single layer that contains reagents, is permeable to the analyte, and excludes red blood cells |

The '862 patent is a continuation-in-part of the '247 patent.[10] It is directed at providing glucose readings which are not affected by the level of red blood cells in the blood sample.[11] '862 patent at 2:49-53. Prior methods of preventing red blood cells from interfering with the readings while allowing glucose to be measured consisted of adding a layer to the test strip which filtered

[10] A continuation-in-part is an application filed during the lifetime of an earlier nonprovisional application, repeating some substantial portion or all of the earlier nonprovisional application and adding matter not disclosed in the said earlier nonprovisional application. *See* Manual of Patent Examining Procedure § 201.08.

[11] In prior methods of glucose testing, blood samples with high levels of red blood cells result in readings that are lower than the true value, while blood samples with low levels of red blood cells result in readings that are higher than the true value. *See* '862 patent at 2:23-33.

out red blood cells, in addition to the layer which contains the substances used for the electrochemical detection of the glucose (the reagent layer). '862 patent at 2:33-38. Using two separate layers added extra steps to the manufacturing process, which led to increased costs and decreased precision. '862 patent at 2:39-42. In order to limit interference from red blood cells without the added manufacturing costs and degraded performance, the inventors of the '862 patent created an "integrated reagent/blood separation layer" which, in one layer, contains the reagents for electrochemical detection of glucose and also excludes red blood cells while allowing glucose to pass through. '862 patent at 3:8-13.

LifeScan proposes that "an . . . integrated reagent/blood separation layer" be construed as "a single layer that contains reagents, is permeable to the analyte, and provides a barrier to the passage of red blood cells."[12] LifeScan's proposal appears consistent with the plain language of the disputed terms and the object of the integrated reagent/blood separation layer, as discussed above.

In contrast, defendants seek a construction which states that the integrated reagent/blood separation layer is silica and/or created through a "sol-gel process." For the reasons stated above, limiting the claim to silica is not warranted. Likewise, defendants offer no compelling justification for reading a "sol-gel process", which is not mentioned anywhere in the patent, into the claim language.

Defendants also argue that LifeScan's proposal that the integrated reagent/blood separation layer be construed as providing "a barrier to the passage of red blood cells" is incorrect because the invention needs to exclude red blood cells, not merely act as a barrier, in order to achieve glucose readings which are not affected by the level of red blood cells in the sample.[13] I agree. Indeed, the specification states that the integrated reagent/blood separation layer is "effective to *exclude* blood cells." '862 patent 3:8-13 (emphasis added); *see also id.* at 7:6-9 ("Reactants such

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[12] An analyte is "a chemical substance that is the subject of chemical analysis." *See* http://www.merriam-webster.com/dictionary/analyte.

[13] The level of red blood cells in blood is known as hematocrit. *See* http://www.merriam-webster.com/dictionary/hematocrit.

as enzyme, mediator and glucose move freely within this zone, but interfering species such as red blood cells containing oxygenated hemoglobin are excluded.").

For the reasons stated above, I construe "an . . . integrated reagent/blood separation layer" as "a single layer that contains reagents, is permeable to the analyte, and excludes red blood cells."

**E. *Matrix* ('862 patent, claims 1, 22)**

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| ordinary meaning<br>or<br>Substance or structure in which something is contained | A *network* that affects the sample being tested; in this case, a network that allows the analyte being tested in the blood sample to pass while excluding from the layer other interfering materials in the sample | Substance or structure in which something is contained |

LifeScan proposes that "matrix" be given its ordinary meaning (not construed) or construed as "substance or structure in which something is contained." "Matrix" is not defined in the patent, but LifeScan's proposed construction is consistent with the ordinary meaning of "matrix." For example, the American Heritage Dictionary defines matrix as "a situation or surrounding substance within which something else originates, develops, or is contained." *See* https://ahdictionary.com/word/search.html?q=matrix.

In contrast, defendants propose a construction which includes unwarranted limitations: "a network that affects the sample being tested; in this case, a network that allows the analyte being tested in the blood sample to pass while excluding from the layer other interfering materials in the sample." Much of defendants' proposed construction relates to the integrated reagent/blood separation layer's role in enabling the glucose to be tested without interference from red blood cells in the blood sample. But the surrounding claim language already states that the "matrix" excludes blood cells while allowing access to glucose. *See* '862 patent at 11:47-50, 12:67-13:3 ("matrix effective to exclude blood cells from the surface of the first conductive element while permitting access to the first conductive element by soluble electroactive species"). Reading this

function into the term matrix itself would render the surrounding language superfluous.

Consistent with its ordinary meaning, I construe "matrix" as "substance or structure in which something is contained."

**F. *Matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species* ('862 patent, claims 1, 22)**

| LifeScan's proposed construction | Defendants' proposed construction | Court's construction |
|---|---|---|
| *Matrix* that provides a barrier to the passage of blood cells while permitting access to the first conductive element by soluble electroactive species. | **Objection:** Compound defined by its functionality only is indefinite.<br>**Alternative Constructions:**<br>1. A silica *matrix* whose pore size has been controlled to allow glucose to pass while excluding the red blood cells in the sample sufficiently to render the strip substantially insensitive to variability in red blood cell counts of patients.<br>2. A *matrix* whose pore size has been controlled to allow glucose to pass while excluding the red blood cells in the sample sufficiently to rend [sic] the strip substantially insensitive to variability in red blood cell counts of patients. | *Matrix* that excludes red blood cells while permitting access…by soluble electroactive species. |

LifeScan proposes that "matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species" be construed as "matrix[14] that provides a barrier to the passage of blood cells while permitting access to the first conductive element by soluble electroactive species." Defendants propose constructions which state that the matrix's "pore size has been controlled to allow glucose to pass while excluding the red blood cells in the sample sufficiently to render the strip substantially insensitive to variability in red blood cell counts of

[14] As noted above, I construe "matrix" as "substance or structure in which something is contained."

patients."[15]

Reading in the pore size limitation is not warranted. The single sentence from the prosecution history which LifeScan references (Dkt. No. 417 at 25) does not show that the patentee "unequivocally and unambiguously" disclaimed a meaning of matrix other than one which relies on pore size to exclude blood cells. *Biogen Idec*, 713 F.3d at 1094.

Consistent with the reasoning and constructions above, I construe "matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species" as "matrix that excludes red blood cells while permitting access … by soluble electroactive species."[16]

[15] Defendants offer two alternative constructions. The first proposed construction limits the matrix at issue to a "silica matrix"; the second proposed construction does not. In addition, in their claim construction brief, defendants' second proposed construction construes the matrix as rendering the test strip "substantially insensitive to variability in red blood cell counts of patients [sic] hematocrit of patients [sic]." This construction (and apparent typographical error) was not disclosed in the parties' joint claim chart. Dkt. No. 409 at 22. Rather, there both of defendants' proposed alternative constructions construed the matrix as rendering the test strip "substantially insensitive to variability in red blood cell counts of patients. *Id*. In any event, I see no material difference between rendering the test strip insensitive to variability in red blood cell counts of patients, and rendering the test strip insensitive to variability in the hematocrit of patients, given that hematocrit refers to the level of red blood cells in blood. *See supra* n.13.

[16] LifeScan seeks a construction which includes the terms "to the first conductive element" in place of the ellipsis. That language appears verbatim in the claims at issue. But the portion of the claims which the parties have asked me to construe, "matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species," specifically excludes that language. Accordingly, while the claim, as construed, reads "matrix that excludes red blood cells while permitting access [to the first conductive element] by soluble electroactive species," the bracketed language is not itself part of the construction; it is the original language of the claim which corresponds to the ellipses in the construction.

## CONCLUSION

I construe the disputed terms as follows:

| Term | Construction |
|---|---|
| A filler having both hydrophilic and hydrophobic surface regions | Additive having some surface regions that lack an affinity for water and some surface regions that have an affinity for water |
| Network | Structure |
| A filler . . . that forms a network upon drying | Additive that forms a structure upon drying that excludes red blood cells while allowing glucose to pass through |
| A[n] . . . integrated reagent/blood separation layer | A single layer that contains reagents, is permeable to the analyte, and excludes red blood cells |
| Matrix | Substance or structure in which something is contained |
| Matrix effective to exclude blood cells . . . while permitting access . . . by soluble electroactive species | Matrix that excludes red blood cells while permitting access…by soluble electroactive species |

The parties shall attend a Case Management Conference on December 16, 2014 at 2:00 p.m. On or before December 9, 2014, the parties shall file a Joint Case Management Statement proposing either a joint case management schedule through trial or competing schedules.

**IT IS SO ORDERED**.

Dated: November 10, 2014

WILLIAM H. ORRICK
United States District Judge

## APPENDIX: CLAIMS AT ISSUE

The disputed terms in the '247 patent appear in claims 1 and 24. Claims 1 and 24, with the disputed terms italicized, recite:

> Claim 1. A disposable glucose test strip for use in a test meter of the type which receives a disposable test strip and a sample of blood from a patient and performs an electrochemical analysis of the amount of glucose in the sample, comprising:
>
> (a) a substrate;
>
> (b) a reference electrode;
>
> (c) a working electrode, said working electrode comprising a conductive base layer disposed on the substrate and a first working coating disposed over the conductive base layer, said first working coating comprising *a filler having both hydrophobic and hydrophilic surface regions* such that it *forms a network upon drying*, an enzyme effective to oxidize glucose, and a mediator effective to transfer electrons from the enzyme to the conductive base layer; and
>
> (d) means for making an electrical connection between the reference and working electrode and a glucose test meter.
>
> Claim 24. A method for making a disposable test strip for the electrochemical detection of glucose, comprising the steps of:
>
> (a) applying working and reference electrode tracks to a substrate;
>
> (b) applying a conductive base layer in contact with the working electrode track; and
>
> (c) applying a working layer over the conductive base layer, wherein the working layer comprising *a filler having both hydrophobic and hydrophilic surface regions* such that it *forms a network upon drying*, an enzyme effective to oxidize glucose, and a mediator effective to transfer electrons from the enzyme to the conductive base layer.

The disputed terms in the '862 patent appear in claims 1, 2, 11, 22, 23. Those claims, with the disputed terms italicized, recite:

> Claim 1. A disposable test strip for use in a test meter which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising:
>
> (a) a substrate;
>
> (b) a first conductive element disposed on the substrate;
>
> (c) a second conductive element disposed on the substrate in sufficient proximity to the first conductive element to allow the completion of an electrical circuit between the first and second conductive elements when a sample of blood is placed on the test strip;

(d) *a* non-conductive *integrated reagent/blood separation layer* disposed over the first conductive element, said integrated reagent/blood separation layer comprising reagents for the electrochemical detection of the analyte dispersed in a non-conductive *matrix effective to exclude blood cells* from the surface of the first conductive element *while permitting access* to the first conductive element

(e) *by soluble electroactive species*; and

(f) contacts for making an electrical connection between the first and second conductive elements and the test meter.

Claim 2. The test strip of claim 1, wherein the *integrated reagent/blood separation layer* comprises an enzyme for oxidation of glucose and a redox mediator effective to transfer electrons from the enzyme to the first conductive element.

Claim 11. The test strip of claim 1, further comprising an insulation layer disposed over at least the first conductive elements, said insulation layer having a first aperture therein aligned with the first conductive element, wherein the non-conductive *integrated reagent/blood separation layer* contacts the first conductive element through the aperture in the insulation layer.

Claim 22. A method for forming a disposable test strip for use in a test meter which receives a disposable test strip and a sample of blood and performs an electrochemical analysis of the amount of a blood analyte in the sample, comprising:

(a) forming first and second conductive elements on a substrate;

(b) forming a layer of insulation covering the first conductive element, said layer of insulation having a first aperture therein aligned with a portion of the first conductive element in a sample application region; and

(c) forming a *integrated reagent/blood separation layer* layer [sic] disposed on the insulation layer and making contact with the first conductive element through the first aperture in the insulation layer, said *integrated reagent/blood separation layer* comprising reagents for the electrochemical detection of glucose dispersed in a non-conductive *matrix effective to exclude blood cells* from the surface of the first conductive element *while permitting access* to the first conductive species *by soluble electroactive species*, whereby the first conductive element is isolated from direct contact with a sample placed on the test strip.

Claim 23. The method of claim 22, wherein the reagent layer is a non-conductive *integrated reagent/blood separation layer*.